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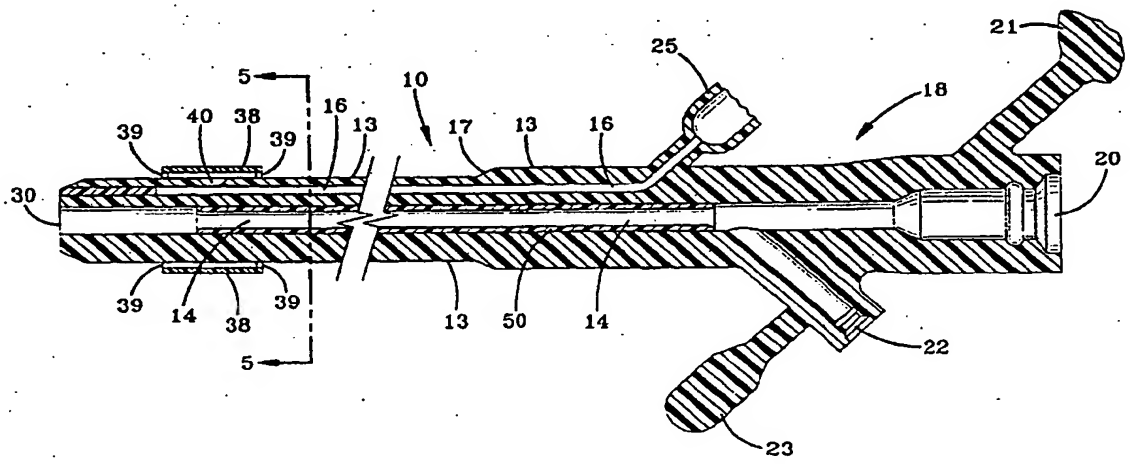

(57) Abstract

An enteral feeding device (10) for feeding directly into the gastrointestinal tract is provided with a tube (12) having an outer (13) and an inner surface, and with the inner surface encompassing a feeding lumen (14) and being coated with a substituted and/or unsubstituted poly(p-xylene) polymer (50) to retard the deterioration and clogging of the device. Examples of such devices are nasogastric tubes, gastrostomy tubes and jejunostomy tubes.

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ENTERAL FEEDING DEVICE

TECHNICAL FIELD

The present invention relates generally to a tube for use in the enteral feeding of a nutritional product directly into the gastrointestinal tract, and more particularly to an enteral feeding tube coated with a poly(p-xylene) polymer.

BACKGROUND OF THE INVENTION

Many individuals in health care facilities are able to achieve sufficient caloric intake through eating prepared meals. However, a sizable number of such patients are unable to ingest enough food to meet their bodies' needs. Examples of these individuals would include burn patients, whose daily caloric needs are often in excess of 5,000 calories; critically ill, weak or comatose patients, who may be unable to chew their food; and patients suffering from cancer of the esophagus, who may be unable to swallow their food. For many of these patients, caloric supplementation through enteral feeding is desired. In response to this problem, liquid nutritional products have been developed for enteral feeding. Enteral feeding may utilize a tube to transport a liquid nutritional product from a container directly into the patient's stomach or intestine.

A first example of a tube for use in the enteral feeding of a liquid nutritional product directly into the gastrointestinal tract is a nasogastric tube, which may extend through a patient's nasal cavity, down the esophagus to the stomach. A second example of a tube for use in the enteral feeding of a liquid nutritional product directly into the gastrointestinal tract is a gastrostomy tube which may extend through a patient's abdominal wall and stomach wall for feeding directly into the stomach. A third example of a

tube for use in the enteral feeding of a liquid nutritional product directly into the gastrointestinal tract is a jejunostomy tube which may extend either through the lumen of a gastrostomy tube and thence into the patient's intestine, or through the patient's abdominal wall and intestinal wall, in either case facilitating feeding directly into the intestine.

One reason why a tube for enteral feeding of a liquid nutritional product directly into the gastrointestinal tract may have to be removed is clogging primarily due to the coagulation of an enteral nutritional food product. A second reason is degradation of the tube. Furthermore, a patient may accidentally or intentionally remove a feeding tube thus requiring the insertion of a replacement tube. Premature replacement of a feeding tube causes the patient to be subjected to the inconvenience, cost, and retraumatization associated with this procedure.

It is thus apparent that the need exists for an improved liquid nutritional feeding tube which reduces degradation and clogging.

There is disclosed herein a tube for use in enteral feeding directly into the stomach or intestine of a mammal comprising a tubular member having an inner and an outer surface, said inner surface being coated with a substituted and/or unsubstituted poly(p-xylene) polymer. In one embodiment of the invention, the outer surface of the tube is coated with said poly(p-xylene) polymer. As used herein and in the claims "parylene" and "poly (p-xylene) polymer" are used interchangeably.

The present invention provides a tube for enteral feeding directly into the stomach or intestine of a mammal which reduces the problems associated with clogging and with degradation, and lessens the frequency of replacement of enteral tube feeding devices due to these problems.

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Other aspects and advantages of the invention will be apparent from the following description, the accompanying drawings and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a gastrostomy tube in accordance with the present invention.

Fig. 2 is a longitudinal cross sectional view taken on a greatly enlarged scale along line 2-2 of Fig. 1.

Fig. 3 is a longitudinal cross sectional view similar to Fig. 2, but of a modified embodiment of the invention.

Fig. 4 is a fragmentary cross-section of a conventional tube following testing over a period of months.

Fig. 5 is a fragmentary cross-section of a tube in accordance with the present invention along line 5-5 of Fig. 2.

Fig. 6 is a fragmentary cross-section of a tube in accordance with the present invention along line 6-6 of Fig. 3.

Fig. 7 is a perspective view of another gastrostomy tube which may be employed in the practice of the present invention.

Fig. 8 is a diagrammatic representation of a jejunal feeding tube which may be employed in the practice of the present invention.

Fig. 9 is a diagrammatic representation of a jejunostomy tube which may be employed in the practice of the present invention.

Fig. 10 is a perspective view of a device for feeding a nutritional product directly into the stomach which may be employed in the practice of the present invention.

Fig. 11 is a diagramatic representation of a nasogastric tube which may be employed in the practice of the present invention.

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DETAILED DESCRIPTION OF THE INVENTION

In tubes used for the enteral feeding of liquid nutritional products into the stomach or intestine of a mammal such as gastrostomy tubes, clogging of the tube can be caused by coagulated enteral nutritional formulas, or by crushed medications or other solids introduced into the tube. Currently, users of such tubes may flush a clogged feeding tube with a fluid, such as water, in an attempt to restore the patency of the lumen. If the flushing is unsuccessful, the tube is generally replaced with a new one. Thus the patient is subjected to the inconvenience, cost and trauma associated with the replacement procedure.

In tubes used for enteral feeding into the stomach or intestine of a mammal, deterioration also presents a significant problem. Enteral feeding tubes are typically comprised of silicone rubber, and microorganisms, such as Candida tropicalis, Candida albicans, Torulopsis glabrata, and others can attach themselves to the surface of the silicone rubber. Under normal patient health conditions, these microorganisms pose no problems. However, in patients whose immune systems may be compromised (for example - cancer or AIDS patients) microorganisms can proliferate internally and the patient cannot fight them with their normal immune systems.

Of course, microorganisms only cause a problem after they have been introduced into a patient's body, but that is more easily done than might be expected. For example, skin yeasts can be present on unclean hands, such that hand contact with the food inlet port may accidently introduce yeast into the tube. This accidental contact can occur when cleaning the area, or by improper handling of the tube.

Once any of these organisms enters an enteral feeding tube there is the potential for a problem. As

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microorganisms attach to a tube wall they give off metabolic byproducts and carbon dioxide as they grow. The metabolic byproducts can degrade the tube wall. Subsequent propagation of the microorganisms into the area weakened by the degradation can cause further degradation of the tube. Sometimes, the growth extends into the wall in an elongated fashion, such that when the growth reaches the outside of the tube, pin hole size apertures are formed, which apertures present the potential for leakage.

This growth of microorganisms and the accompanying degradation of the tube causes the tube to lose its elastomeric properties (e.g. tensile strength, hoop strength, recovery, etc.). As it loses its elastomeric properties, the tube loses its hoop strength resulting in a misshapen tube. Also, loss of its elastomeric properties causes the tube to be more easily flattened, especially if nurses attempt to slide crushed medications through the tube by squeezing the tube.

Additionally, as the microorganisms attach and multiply into the feeding lumen the smooth walls of the lumen become pitted. Then as gastric acid mixes with the protein in the liquid nutritional product coagulation occurs, with this coagulation having an increased tendency to attach to the pitted tube wall. Over time, clogging of the tube can become a problem. The problem of clogging is so pronounced that it is one of the most frequent complaints by nurses relating to enteral feeding tubes.

Having reference to the drawings, attention is directed first to Figs. 1 and 2 which illustrate an example of a gastrostomy tube embodying this invention designated generally by the numeral 10. This gastrostomy tube 10 is an example of a replacement, or secondary, gastrostomy tube which is employed when the patient already has a healthy, mature stoma tract. The replacement gastrostomy tube may be inserted into the stomach through the stoma following the removal of a primary gastrostomy tube, which will be

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described later. The basic components of this exemplary device are a tubular member 12 having an outer surface wall 13, with the tubular member 12 enclosing a feeding lumen 14 and a fluid flow channel 16. The fluid flow channel 16 is also referred to in the trade as a balloon lumen.

At one end end 17 of the tubular member 12 is port housing 18. The port housing includes as its primary components, a main food inlet port 20 equipped with a main port closure 21, a Y-port 22 similarly equipped with a Y-port closure 23, and a fluid inlet port 25 equipped with a valve means 26 preferably of the type known as a one-way valve. At the other end 28 of the flexible tubular member 12 is food outlet port 30. An expandable component member 38, often referred to as a balloon, is secured preferably by means of an adhesive bond 39 to outer surface wall 13. A fluid access port 40 extends between the fluid flow channel 16 and the outer surface wall 13 located centrally of the expandable component member. As such, the fluid flow channel is capable of passing fluid from the valve means 26 shown in Fig. 1 into expandable component member 38 so as to permit the expansion of the balloon.

As can be seen in Fig. 1 a retention device 43 is also provided having a triangular configuration and a plurality of vent holes. A device for enteral feeding according to the present invention is preferably fabricated from 100% medical grade silicone rubber, with the exception of the coating which is described below and the components of the valve means 26.

Fig. 2 discloses this invention comprising a layer 50 of a poly(p-xylene) polymer (parylene) on the inner surface of the tubular member. In another embodiment of the invention shown in Fig. 3, a layer 60 of a poly(p-xylene) polymer coats the outer surface of the tubular member. In all other respects these two embodiments are substantially the same as described above.

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Poly(p-xylene) polymers are well known. The preferred choice for this invention is the parylene supplied by Specialty Coating Systems (a subsidiary of Union Carbide) of Indianapolis, Indiana. Parylene has been used to coat orthopedic products to render their materials compatible with body tissue, and to serve as a dry film lubricant. It has also been used as an intimal lining to promote tissue growth and adhesion where it is desired to stimulate tissue growth. Furthermore, it has been used in general insulation resistance via encapsulation to isolate materials and devices from body fluid, moisture, and ionic contaminants. Finally, it has been used to coat metal to prevent corrosion.

Patents involving parylene or poly(p-xylene) polymers include U.S. Patent No. 3,826,244 to Salcman et al for Thumbtack Microelectrode and Method of Making Same, and U.S. Patent No. 4,225,647 for Articles Having Thin, Continuous, Impervious Coatings.

The parylene is coated onto an outer and/or inner wall of a tubular member by a deposition process. First the parylene is heated to approximately 150°C at 1 Torr, resulting in conversion to a gaseous dimer. The dimeric gas is forced downstream into a pyrolysis zone as the gas pressure in the vaporization zone rises. In the pyrolysis zone the temperature rises to approximately 690°C at 0.5 Torr, thereby splitting the dimeric molecules into highly reactive monomers. In the preferred embodiment of this invention parylene-N is used.

The monomer molecules continue to respond to pressure, flowing into the deposition chamber where they disperse, deposit and polymerize into a clear linear film on all surfaces which are exposed to the gas. Deposition takes place in a vacuum environment of approximately 0.1 Torr and near ambient temperature (approximately 35°C). Coating thickness is relatively uniform, with excellent conformity. In this exemplary gastrostomy tube, the tubular member has its entire inner surface coated except for portions located

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within about 1.3 cm (1/2") from the first end and the second end.

In order to determine whether the invention as described above really represented a significant advancement over the prior art, a test was conducted comparing a parylene coated tube with an unprotected (uncoated) silicone tube. In actuality, four tubes of each type were used in the comparative study.

Each of the tubes were contaminated (for purposes of this study) with an enteral nutritional product in which yeasts, isolated from a tube removed from a patient in a clinical environment, were suspended. Re-contamination with yeasts was repeated on a weekly basis for the first several months of the trial. Then, in an attempt to more accurately model a clinical environment, and to hasten the breakdown of the tubes, various bacteria, also isolated from clinical tubes, including Escherichia coli, Enterobacter, Serratia, Citrobacter, Klebsiella, and Pseudomonas were suspended with the yeast in the enteral nutritional product, and recontamination of the tubes was repeated on a daily basis. This occurred approximately four and one-half months after the test began. Additionally, 10 ml of fresh enteral nutritional product, with or without organisms, was passed through each tube at least six times per week. Smears were examined periodically to assure the presence of organisms, especially yeasts, in the nutritional product. The test was suspended after approximately five and one-half months.

Physically, the parylene coated tubes prior to the test appeared to be somewhat less pliable when squeezed than the fresh, uncoated tubes. Meanwhile, the conventional tubes had a soft, rubbery feel. Over the next couple of months, no changes were readily detected. However, in the time period prior to cessation of the study, the conventional tubes began to lose some of their roundness and appeared to be somewhat bumpy. Also, following squeezing of the conventional tubes, the walls did not spring back to their natural round shape as

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quickly as before. The poly (p-xylene) polymer coated tubes did not experience any noticeable decline with respect to their physical characteristics.

At the conclusion of the study, all of the tubes (coated and uncoated) were cut in two near the mid-point of the tube. Five additional tests were then performed. The first test involved a gram stain of a sample of the coagulated enteral nutritional from the interior of the tube. This examination revealed that the yeast organisms were always present in the coagulum. In addition, small gram-positive rod shaped bacteria were also observed. These presumably resulted from contamination of the orifices of the Y-port used to infuse the enteral nutritional and which came from the environment or the skin.

Additionally, at no time were medium sized gram-negative rods observed in the stained smears. This suggested that contamination with enteric and environmental organisms such as Escherichia coli, Enterobacter, Serratia and related bacteria did not occur, in spite of numerous inoculations with these bacteria.

The second test involved the growing of cultures on various media using coagulum from the tubes. This test was performed in order to identify the contaminating microorganisms. Coagulum was plated on blood agar, MacConkey agar and Sabouraud's agar with gentamicin plates. Blood agar medium is a non-selective medium which allows most aerobic organisms to grow. In this study, culture on blood agar medium resulted in the isolation of yeast and diphtheroids. MacConkey agar permits the growth of gram-negative enteric bacteria, but none were isolated following culture, even after inoculation of the enteral nutritional formula therewith. Only yeasts were isolated on the MacConkey agar. The Sabouraud's medium with gentamicin permits the growth of yeasts and inhibits the growth of most bacteria. Only yeasts were isolated.

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Overall, the results of the cultures (shown below in Tables 1 and 2) indicated that each tube (coated and uncoated) contained yeast and gram-positive bacteria, but no gram-negative organisms. Thus the microbial culture results confirmed the morphological data of the organisms observed in the gram-stained smears of the coagulum. The cultures also corroborated the failure to establish gram-negative bacteria in any of the silicone tubes.

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TABLE 1

FINAL CULTURE RESULTS OF PARYLENE COATED TUBES

SAMPLE	BLOOD AGAR	MACCONKEY AGAR	SABOURAUD'S
Tube 1	Yeast - 2 (2 Types) Diphtheroid - 3	Yeast - 2 (1 Type)	Yeast - 3 (3 Types)
Tube 2	Yeast - 2 (2 Types) Diphtheroid - 3	Yeast - 2 (1 Type)	Yeast - 3 (3 Types)
Tube 3	Yeast - 2 (2 Types) Diphtheroid - 3	Yeast - 2 (1 Type)	Yeast - 3 (3 Types)
Tube 4	Yeast - 3 (3 Types) Diphtheroid - 3	Yeast - 2 (2 Types)	Yeast - 3 (3 Types)

1 = light numbers
2 = moderate numbers
3 = heavy numbers

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TABLE 2

FINAL CULTURE RESULTS OF UNCOATED TUBES

SAMPLE	BLOOD AGAR	MACCONKEY AGAR	SABOURAUD'S
Tube 1	Yeast - 2 (3 Types)	Yeast - 1 (1 Type)	Yeast - 1 (1 Type)
	Diphtheroid - 2		
Tube 2	Yeast - 3 (3 Types)	Yeast - 1 (1 Type)	Yeast - 1 (1 Type)
	Diphtheroid - 3		
Tube 3	Yeast - 2 (3 Types)	Yeast - 1 (2 Types)	Yeast - 1 (3 Types)
	Diphtheroid - 2		
Tube 4	Yeast - 1 (3 Types)	Yeast - 1 (2 Types)	Yeast - 1 (3 Types)
	Diphtheroid - 3		

1 = light numbers
2 = moderate numbers
3 = heavy numbers

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The third test involved a longitudinal incision of each of the tube segments. In contrast to new, unused tubes which when cut longitudinally maintained their round shape, the conventional uncoated tubes subjected to this test lost some elasticity and remained open after a longitudinal incision. The appearance of the conventional uncoated tubes subjected to this test and then cut longitudinally resembles the look of tubes from clinical sources when cut longitudinally. A parylene coated tube subjected to the same testing procedure remained in apposition when a longitudinal cut was made, indicating that the wall of the tube was not weakened.

The fourth test involved a visual comparison of the interior walls of the tubes. Swabs were used to clean the inner surface of the tubes. The inner surfaces of all the conventional uncoated tubes had focal to more generalized yellowish deposits. These were deposits of the coagulated enteral nutritional product, within which were yeasts. In contrast, the parylene coated tubes were free from deposits. The inner surfaces had the same white color that was present prior to the study.

The fifth test involved the microscopic evaluation of sections of the tubes. Cross sections of previously cleaned tubes were immersed in acetone for approximately 2 minutes, air dried, then immersed in Wright stain for 30 seconds to 1 minute. After washing and drying, the sections were placed on a glass slide surrounded by methacrylate polymer mounting fluid and covered with a cover glass. The tube degradation was visually assessed. Focal to more generalized areas of penetration by microganisms into the conventional tubes were observed, typically involving 75-85% of the inner surface of the tube. This finding coincided with the depth of penetration often involving up to 20% of the width of the conventional tubes in some areas as shown in Fig. 4, which is a cross sectional representation of the tube

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degradation 99 which was observed in conventional uncoated tubes. Meanwhile, with respect to the parylene coated tubes of this invention, Figs. 5 and 6 are representative cross-sections of the lack of degradation which was observed in any of the parylene coated tubes. (Fig. 5 is a cross-section of the embodiment of Fig. 2 taken along line 5-5 thereof, and Fig. 6 is a cross-section of the embodiment of Fig. 3 taken along line 6-6 thereof.

As can be observed in Fig. 4, there has been microbial growth 99, and especially microbial penetration into the uncoated tube. In addition to Fig. 4 which is a pictorial representation of tube degradation, the results are also set forth in Table 3.

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TABLE 3

MICROSCOPIC EVALUATION OF UNCOATED AND PARYLENE COATED TUBES

UNCOATED

Tube 1 - 80-85% of tube inner surface involved; 10-30% depth of penetration

Tube 2 - 80-85% of tube inner surface involved; 10-25% depth of penetration

Tube 3 - 80-85% of tube inner surface involved; 10-20% depth of penetration

Tube 4 - 75% of tube inner surface involved; 10-30% depth of penetration

PARYLENE COATED

Tube 1 - No focal or generalized areas involved; no evidence of penetration or growth into the wall; some cracks noted

Tube 2 - No focal or generalized areas involved; no evidence of penetration or growth into the wall; some cracks noted

Tube 3 - No obvious focal or generalized areas involved; one area of possible penetration or growth into the wall; but could be an artifact; some cracks noted

Tube 4 - No focal or generalized areas involved; one area of possible penetration or growth into the wall; but could be an artifact; some cracks noted

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Thus it can be appreciated that the parylene coated feeding tubes are superior to the feeding tubes conventionally used today. The feeding tubes of this invention do not develop deposits on the inner surface associated with conventional enteral feeding tubes. Additionally, there was evidence of penetration of the inner wall in the conventional tubes, and an apparent loss of elasticity. In contrast, the parylene coated tubes were (with the exception of a single focal area in one tube) free of microbial penetration of the inner wall surface. In conclusion, in terms of tube degradation due to microbial contamination, the parylene coated tubes outperformed the conventional uncoated tubes.

Referring now to Figs. 7-11 there is shown a variety of additional devices for enteral feeding directly into the gastrointestinal tract of a mammal which may be employed in the practice of the present invention. These devices are only exemplary and one skilled in the art will immediately recognize that a variety of embodiments of such devices are known which could be employed in the practice of the present invention.

Fig. 7 is a perspective view of a primary gastrostomy tube 100. A primary gastrostomy tube of the type shown may be installed, for example, by means of a percutaneous endoscopic gastrostomy (PEG). (A gastrostomy tube of the type shown in Fig. 1 may be employed as a primary gastrostomy tube when placed by a laparoscopic gastrostomy procedure.) A primary gastrostomy tube is a device used for the initial placement in the patient of an enteral feeding tube which passes through the abdominal wall into the stomach. One objective of the use of a primary gastrostomy tube is the formation of a healthy, mature stoma tract which may later facilitate the placement of a replacement, or

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secondary, gastrostomy tube as has already been described herein.

There is shown in Fig. 7 an assembly comprising a primary gastrostomy tube 100 and a tapered dilator 101. If the tubular portion 102 were to be comprised of a material of sufficient rigidity, it could be configured to function as a dilator. However; inasmuch as the preferred materials for the tubular portion 102 are fairly soft and flexible, it is preferred that the dilation of a stoma formed during a PEG procedure is better accomplished by using a tapered dilator 101 of a more rigid material such as a low or medium density polyethylene. An internal retaining member 103 is located at the end of the primary gastrostomy tube which will be disposed within a patient's stomach when the tube is in its operative position. The end 104 of the tubular member 102 which will be disposed externally of the patient's abdomen is joined to the larger end 105 of the tapered dilator 101 by a means for connecting such as a barbed nylon connector 106. Such a primary gastrostomy tube has been described in U.S. Patent 5,080,650. It is the tubular portion 102 of the primary gastrostomy tube which may advantageously be coated with a substituted and/or unsubstituted poly (p-xylene) polymer in accordance with the present invention.

Referring next to Fig. 8 there is shown the use of a jejunal feeding tube 109 with the primary gastrostomy tube 100 which has been installed with its internal retaining member 103 disposed within the stomach 110 of a patient. In this example the excess length of the gastrostomy tube has been cut off to such that about 15 cm of the gastrostomy tube is located exterior of the patient's abdomen. Feeding of the patient may then commence by passing a jejunal feeding tube 109 through the gastrostomy tube 100 into the stomach 110, past the pyloris and into the small bowel. Once in the small bowel the jejunal feeding tube 109 passes through the duodenum 111 and preferably terminates in the area of the jejunum 112. Feeding of the patient can thereafter be

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accomplished using procedures that are well known in the medical arts. A jejunal feeding tube may advantageously be coated with a substituted and/or unsubstituted poly (p-xylene) polymer in accordance with the present invention.

Referring next to Fig. 9 there is shown a jejunostomy tube 115 in its operative position extending through the abdominal wall 116 of a patient into the patient's jejunum 117. The patient's jejunum is secured against the abdominal wall by retaining devices having an internal T-member 118 secured to an external member 119 by a suture 120. The jejunostomy tube 115 is secured by a suitable retaining device 121. Located at the external end of the jejunostomy tube is a port 122 for receiving a nutritional product. A jejunostomy tube may be installed, for example, using a laparoscopic procedure of the type taught in U.S. Patent 5,151,086. The tubular portion of a jejunostomy tube is typically comprised of polyurethane. The tubular portion of a jejunostomy tube may advantageously be coated with a substituted and/or unsubstituted poly (p-xylene) polymer in accordance with the present invention.

Referring next to Fig. 10 there is shown a perspective view of an example of a type of replacement gastrostomy tube 130 having a tubular portion 131, a stretchable internal retaining portion 132 (which is located inside the stomach when installed) and an external retaining member 133 (which is located adjacent to, and external of the patient's abdomen when installed). A stopper member 134 is used to plug the feeding lumen between feedings. Such replacement gastrostomy tubes have been marketed by Ross Laboratories, a Division of Abbott Laboratories, Columbus, Ohio, U.S.A. The tubular portion of this type of replacement gastrostomy tube may advantageously be coated with a substituted and/or unsubstituted poly (p-xylene) polymer in accordance with the present invention.

Referring next to Fig. 11 there is shown a diagrammatic representation of a nasogastric tube 140 which

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extends through a patient's nasal cavity 141 and esophagus 142 to the stomach 143, and may further extend if desired into the intestine 144 (if placed in the intestine the tube may also be referred to as a nasogastrointestinal tube). Such a tube may be employed in enterally feeding directly into the patient's gastrointestinal tract. The tubular portion of a nasogastric tube is typically comprised of polyurethane. A nasogastric (or nasogastrointestinal) tube may advantageously be coated with a substituted and/or unsubstituted poly (p-xylene) polymer in accordance with the present invention.

INDUSTRIAL APPLICABILITY

On any given day, thousands of persons are being tube fed. The enteral feeding industry has long sought ways to reduce retraumatization due to replacement of feeding tubes. Additionally, the industry has sought ways to minimize the potential for problems due to tube clogging and degradation. This invention solves the long felt need. All the advantages of this invention would be found extremely beneficial by physicians, and more importantly by patients. The invention could, for example, take the form of a gastrostomy tube, a replacement gastrostomy tube, a jejunal feeding tube, a nasogastric tube or jejunostomy tube. Additionally the tubes could be of PVC, latex rubber, or polyurethane.

While the form of the devices herein described constitute a preferred embodiment of this invention, it is to be understood that the invention is not limited to these precise forms of devices and that changes may be made therein without departing from the scope of the invention which is defined in the appended claims.

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WHAT IS CLAIMED:

1. A device for enteral feeding directly into the gastrointestinal tract of a mammal comprising a tubular member having an outer and an inner surface, said inner surface encompassing a feeding lumen, and at least a portion of said inner surface being coated with a substituted and/or unsubstituted poly(p-xylene) polymer.

2. A device according to claim 1 wherein said tubular member comprises medical grade silicone rubber.

3. A device according to claim 1 wherein at least a portion said outer surface is coated with said poly(p-xylene) polymer.

4. A device according to claim 1 further comprising a fluid inlet port housing for receiving a liquid nutritional product.

5. A device according to claim 1 wherein said tubular member has a first and a second end, said inner surface being continuously coated from about said first end to said second end.

6. A device for enteral feeding directly into the stomach or intestine of a mammal according to claim 1 wherein the tubular member comprises polyurethane and said device is a nasogastric tube.

7. A device according to any one of claims 1 through 5 wherein said device is a nasogastric tube.

8. A device according to any one of claims 1 through 5 wherein said device is a gastrostomy tube.

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9. A device according to any one of claims 1 through 5 wherein said device is a jejunostomy tube.

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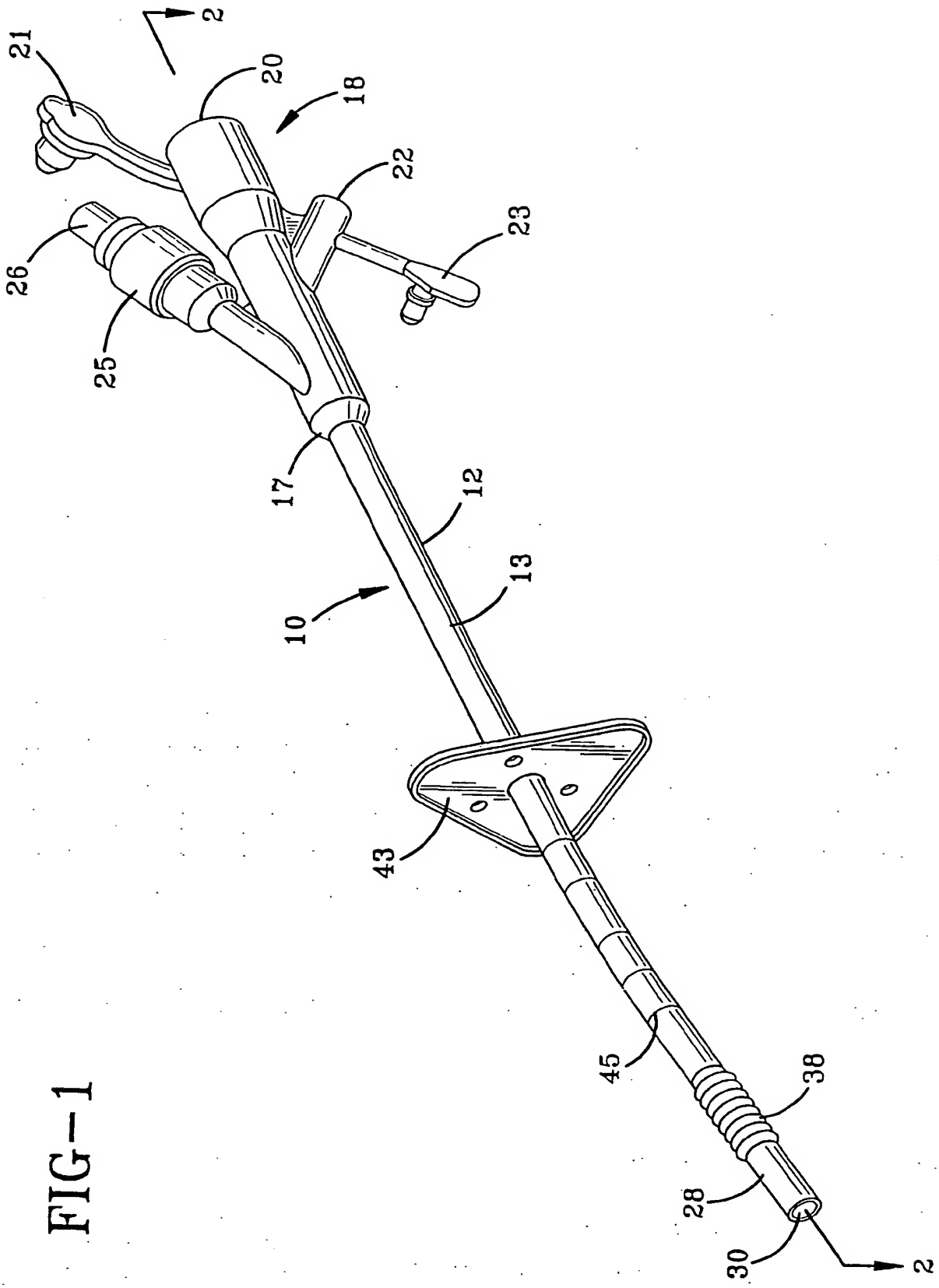

FIG-1

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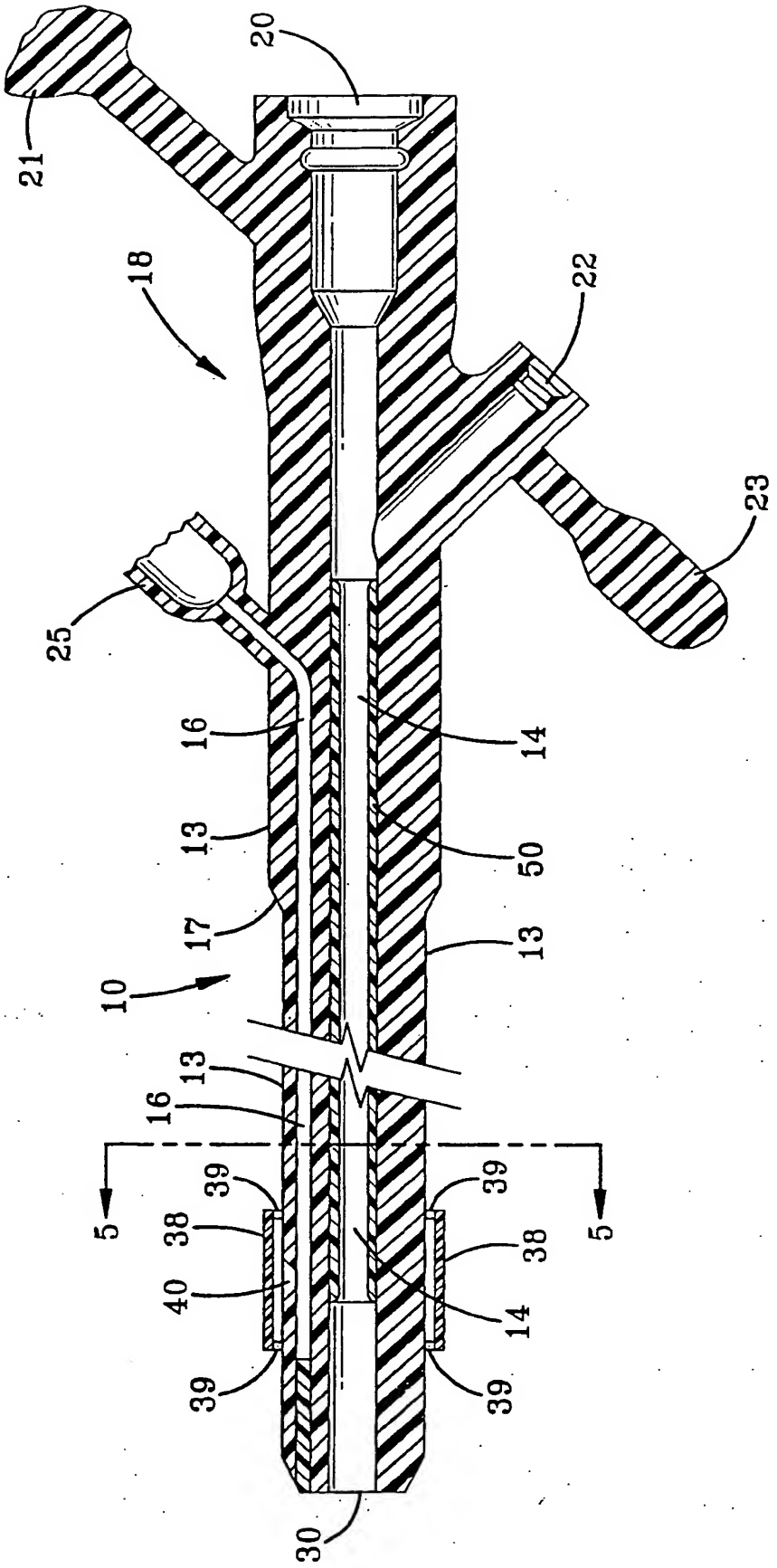
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FIG-2

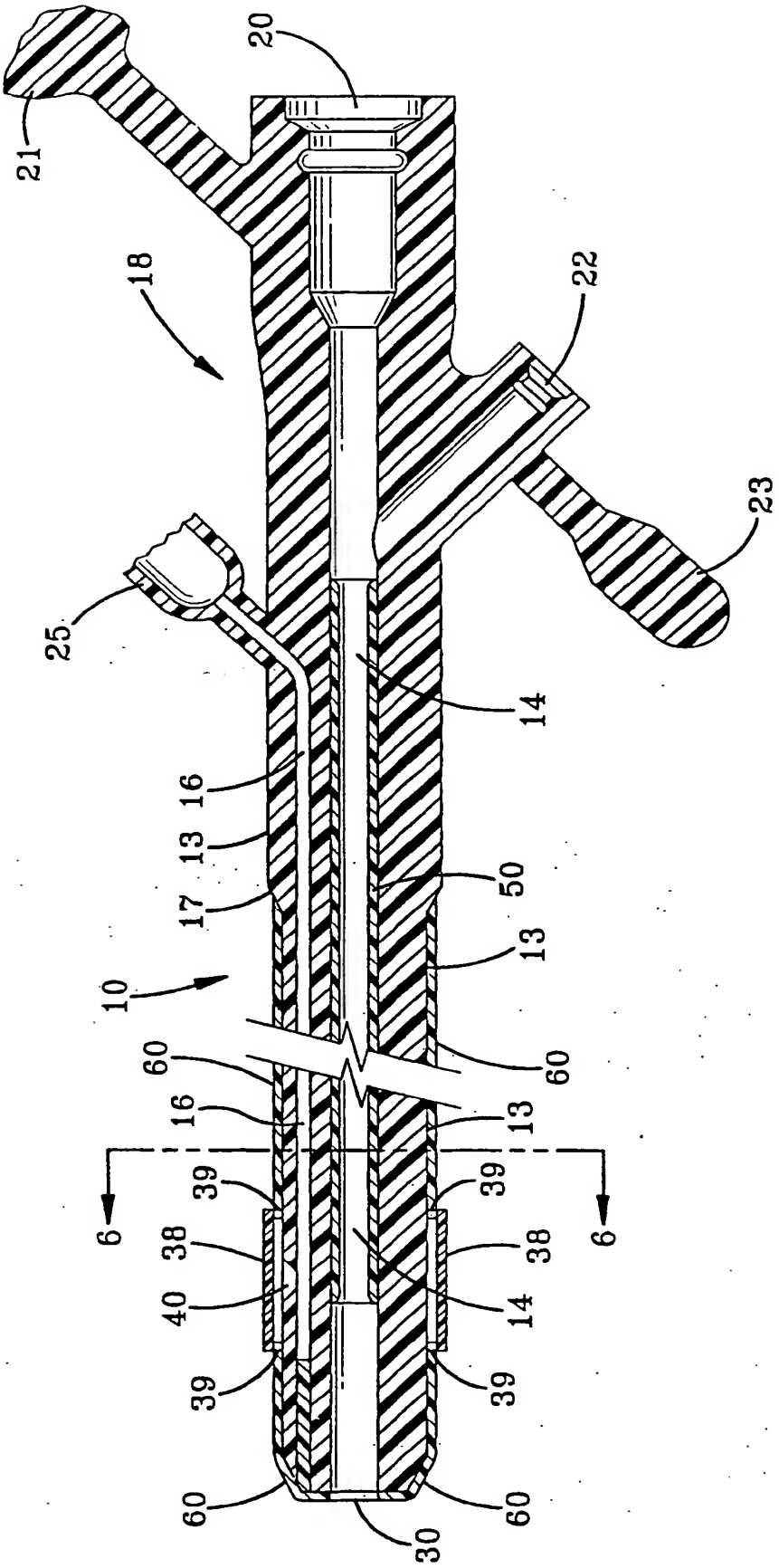

FIG-3

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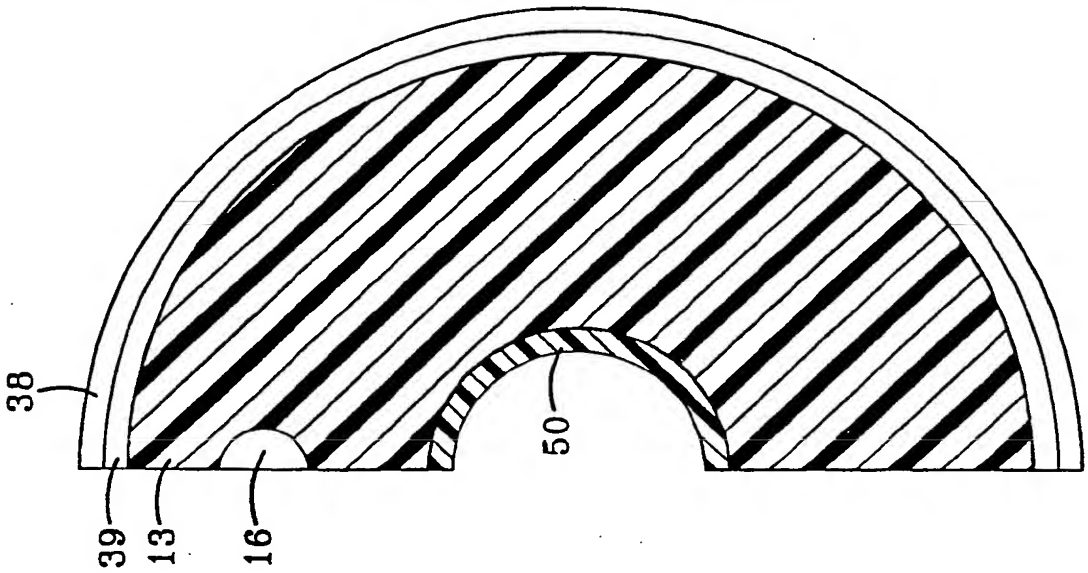

FIG-5

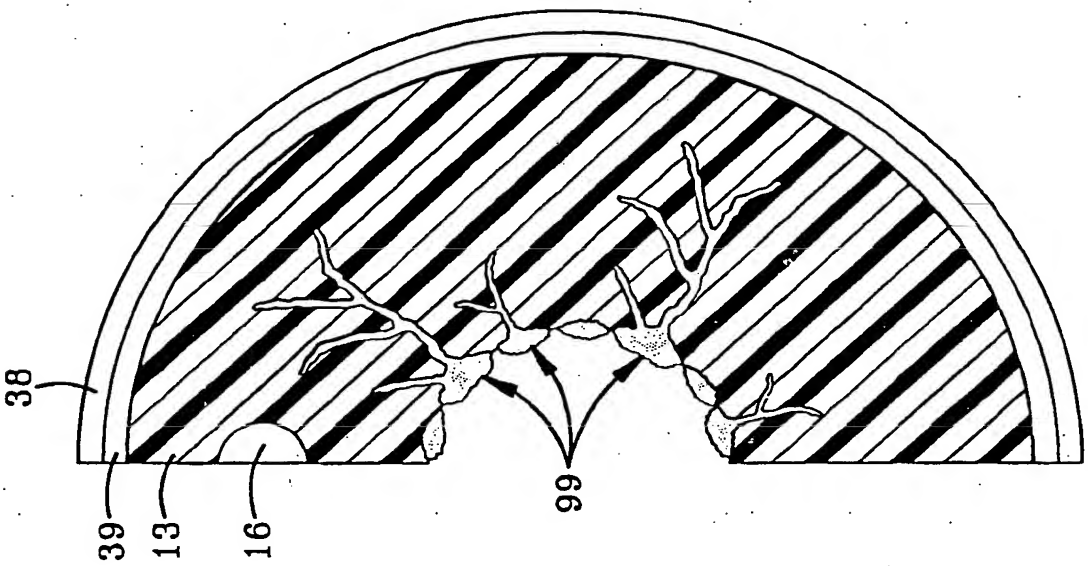

FIG-4

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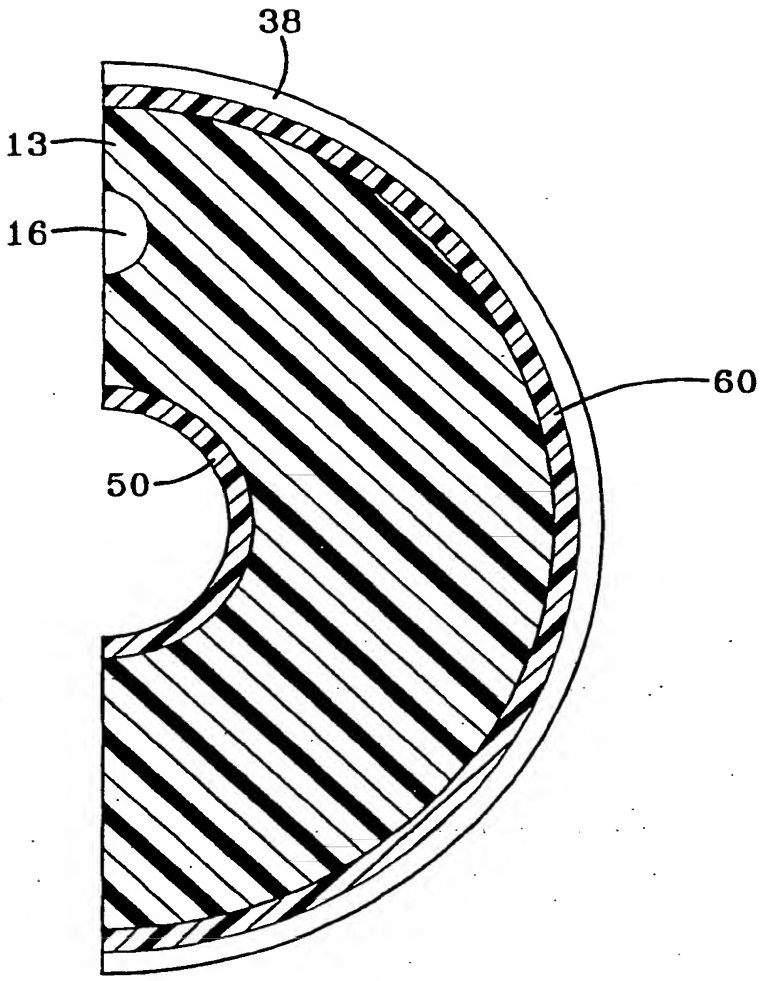

FIG—6

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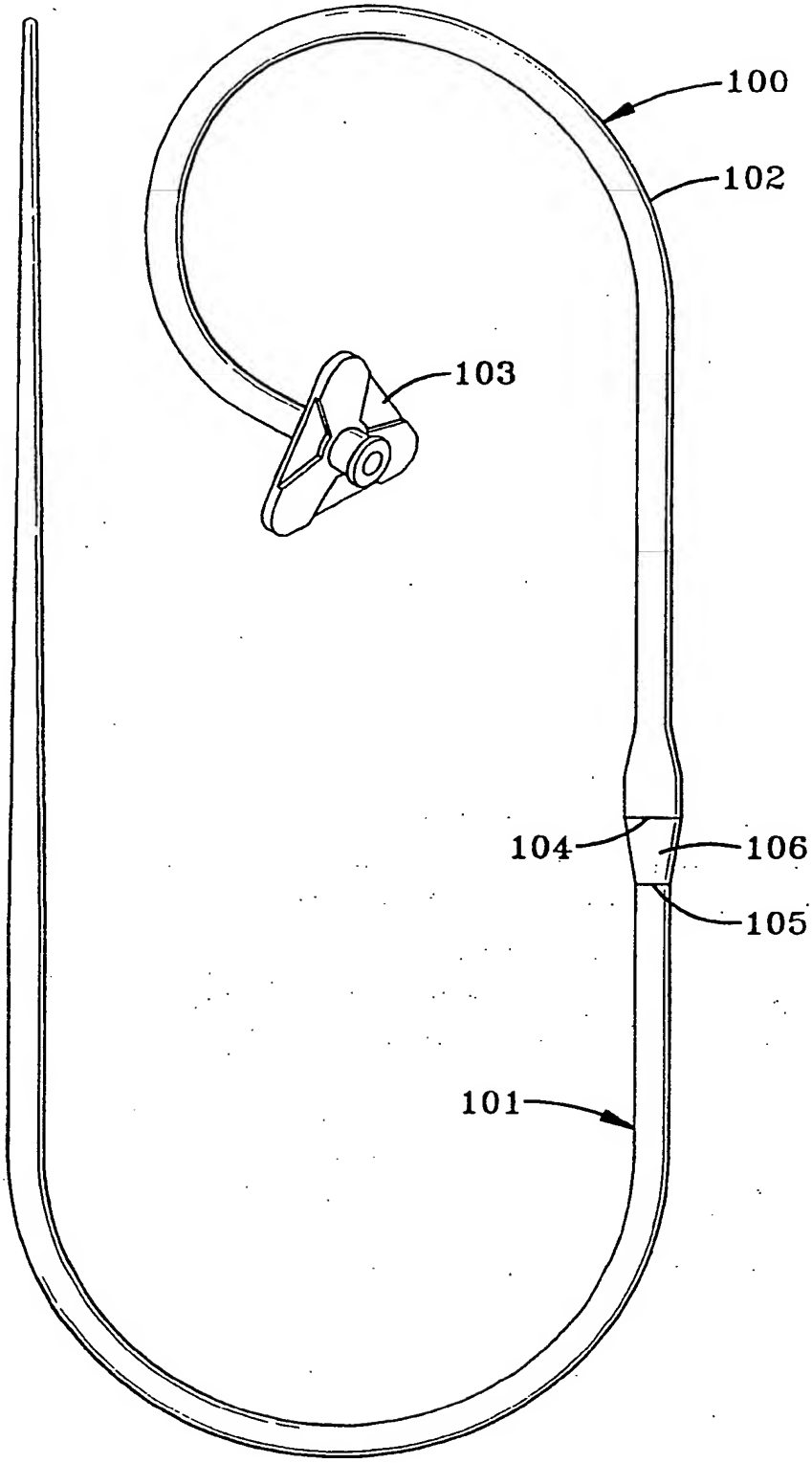

FIG—7

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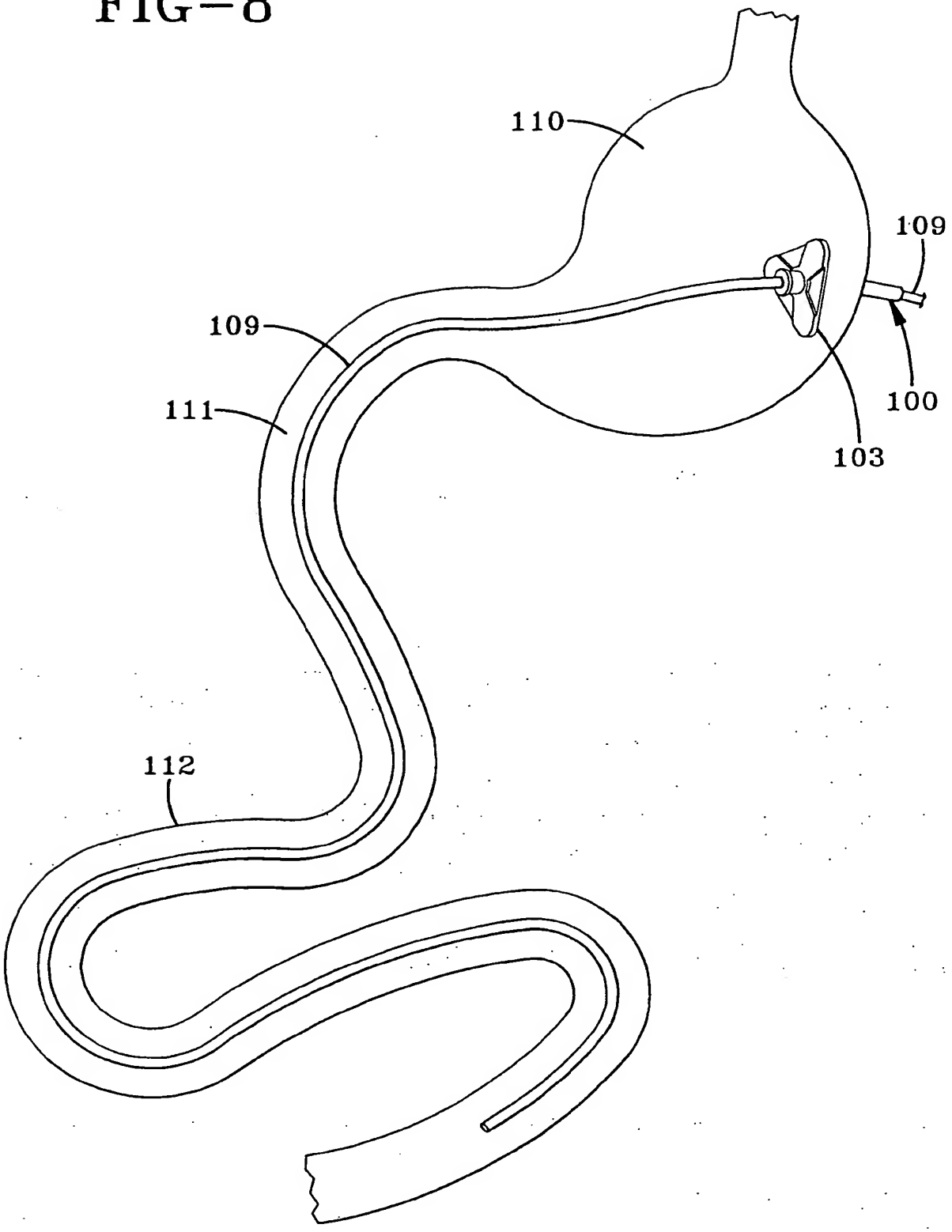
FIG-8



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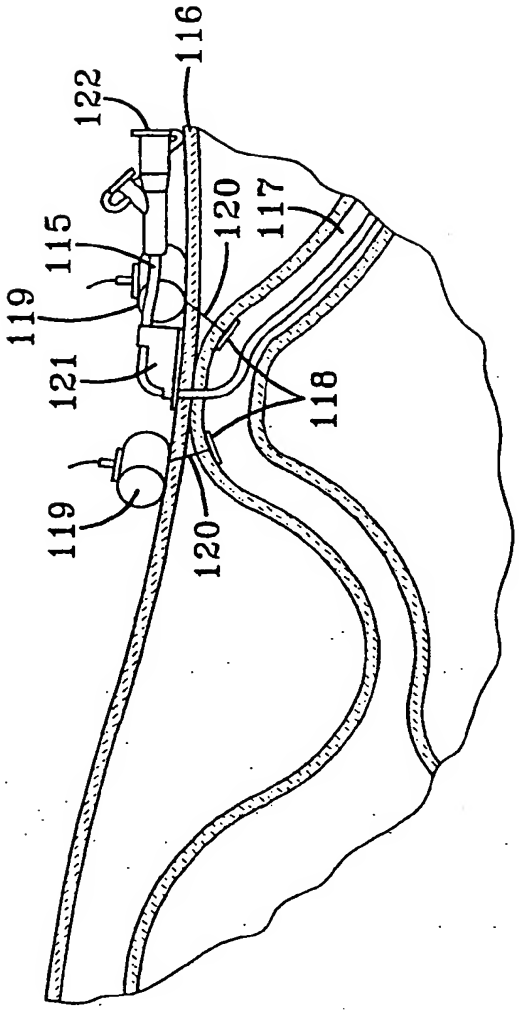
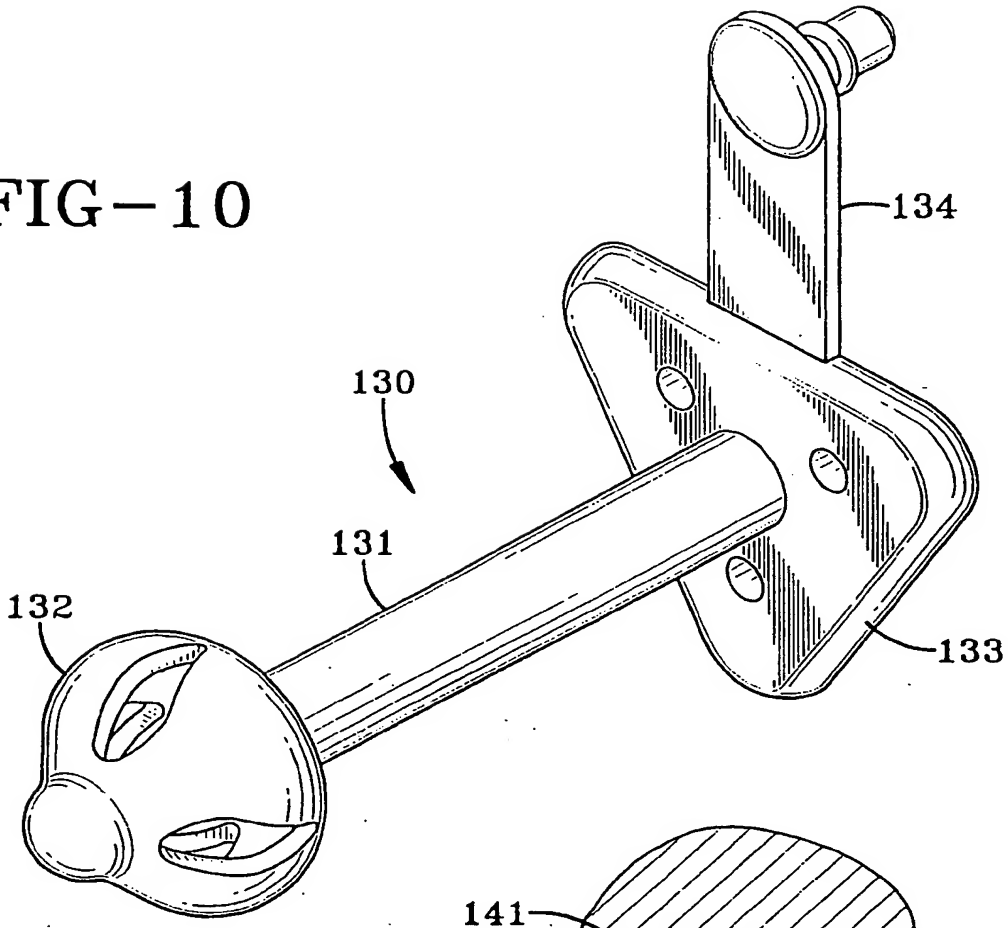


FIG—9

BNSDOCID: <WO___9504564A1_I_>

FIG-10



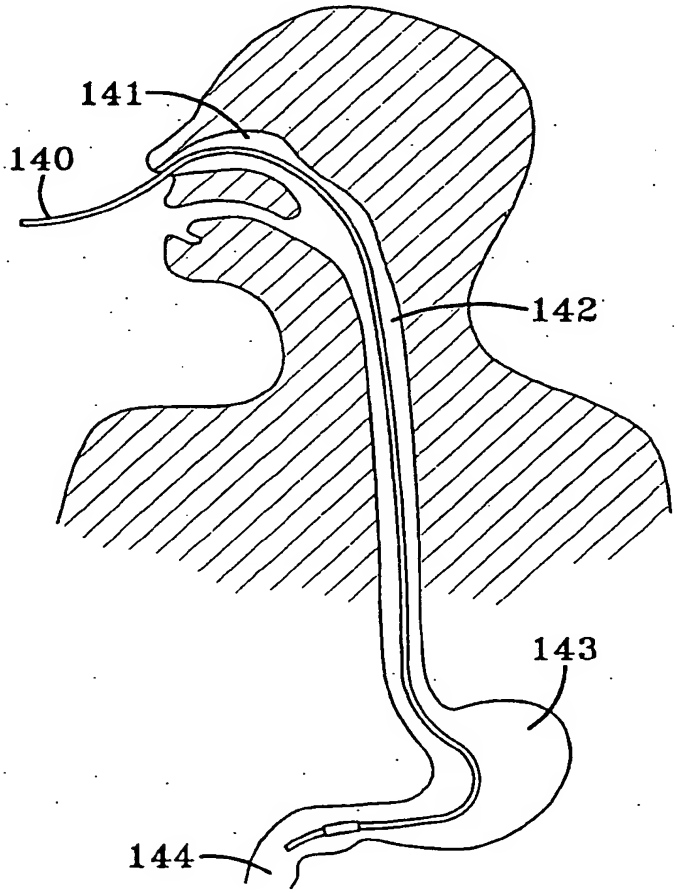


FIG-11

BNSDOCID: <WO___9504564A1_I_>

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/03997

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 5/32, 25/00
US CL :604/266, 280
According to Internati nal Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/264-266, 270, 280, 282

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim N .
Y	US, A, 4,863,424, (BLAKE, III ET AL.), 05 September 1989. See column 4 line 66 through column 5 line 15.	1-9
Y	US, A, 5,032,113, (BURNS), 16 July 1991. See column 4, lines 25-29.	1-9
Y	NOVA TRAN CORPORATION, Pub No. MED4.90, April 1990, PARYLENE - AN INERT COATING FOR CRITICAL BIOMEDICAL APPLICAITONS. See entire document.	1-9
Y	US, A, 4,698,056, (CIANNELLA), 06 October 1987. See column 2, lines 18-20.	1-9
Y	US, A, 4,668,225, (RUSSO ET AL.), 26 May 1987. See entire document.	1-9

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date f th actual completion of the internati nal search
20 JUNE 1994

Date of mailing of the international search report
JUL 19 1994

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